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STATE OF DELAWARE
BOARD OF PHARMACY

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PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, October 21, 2015 9:30 am
PLACE:	Conference Room A, 2 nd Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
APPROVED:	November 18, 2015

MEMBERS PRESENT

Susan Esposito, R.Ph., Professional Member, President
Hooshang Shanehsaz, R.Ph., Professional Member, Vice President
Kimberly Robbins, R.Ph., Professional Member
Tejal Patel, PharmD, Professional Member
Bonnie Wallner, R.Ph., Professional Member
Joli Martini, R.Ph., Professional Member
Julia Wheatley, Public Member
Jay Galloway, Public Member

MEMBERS ABSENT

Kenneth Sellers, Public Member

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Eileen Kelly, Deputy Attorney General
Christine Mast, Administrative Specialist III
Michelle McCreary, Pharmacist Compliance Officer

ALSO PRESENT

Bill Irvin
Debbie Hamilton
Jeff Timmerlin
Jeff Lentowski
Harish Chhibba
Brenda Matthews
Jay Patel
Blair Heckel
Amy Bixler
Jaime Frink
Kevin Morgan
Joseph P Peoples
Jen Raiby
Andrew Wilson
Judy Balcombe

CALL TO ORDER

Ms. Esposito called the meeting to order at 9:30 a.m.

REVIEW OF MINUTES

A motion was made by Mr. Shanehsaz and seconded by Ms. Wheatley, to approve the meeting minutes for September 16, 2015. Ms. Martini abstained, the motion carried.

PRESIDENT'S REPORT

No Report

UNFINISHED BUSINESS

Complaint Status

13-09-11 – Assigned to Hearing Officer
13-12-11 – Assigned to Hearing Officer
13-19-11 – Forwarded to Office of Attorney General
13-01-13 – Forwarded to Office of Attorney General
13-04-13 – Forwarded to Office of Attorney General
13-05-13 – Forwarded to Office of Attorney General
13-06-13 – Forwarded to Office of Attorney General
13-20-13 – Forwarded to Office of Attorney General
13-26-13 – Assigned to Hearing Officer
13-01-14 – Forwarded to Office of Attorney General
13-03-14 – Assigned
13-04-14 – Assigned
13-05-14 – Assigned
13-06-14 – Forwarded to Office of Attorney General
13-07-14 – Forwarded to Office of Attorney General
13-08-14 – Assigned
13-09-14 – Forwarded to Office of Attorney General
13-10-14 – Forwarded to Office of Attorney General
13-11-14 – Forwarded to Office of Attorney General
13-12-14 – Forwarded to Office of Attorney General
13-13-14 – Assigned
13-14-14 – Forwarded to Office of Attorney General
13-15-14 – Assigned
13-16-14 – Assigned
13-17-14 – Assigned

Re-Review Tabled Application

IV Solutions – a motion to table the application for more information was made by Ms. Robbins and seconded by Ms. Patel. The motion unanimously carried.

Trigen Laboratories – a motion to approve the application was made by Mr. Shanehsaz and seconded by Ms. Wallner. The motion unanimously carried.

Empire Specialty Pharmacy – a motion to propose to deny the application was made by Mr. Shanehsaz and seconded by Ms. Robbins. The motion unanimously carried

Cantrell Drug Company – a motion to approve the application was made by Ms. Robbins and seconded by Ms. Wallner. The motion unanimously carried.

A motion to amend the agenda to add the application from Unique Pharmaceutical was made by Ms. Martini and seconded by Mr. Shanehsaz. The motion unanimously carried.

Unique Pharmaceutical - a motion to approve the application was made by Ms. Martini and seconded by Mr. Shanehsaz. The motion unanimously carried.

Deliberations on Proposed Changes to Regulation 3.8

Ms. Kelly brought the hearing to order. Written comment received during the comment period was entered into the record. Exhibit #1 received on September 25, 2015 from Ms. Lisa Bowe, PharmD in support of the regulation change. Exhibit #2 received on September 29, 2015 from Mr. Christopher Smith, National Association of Chain Drug Stores, Director of Federal Public Policy was not in support of the regulation change. The Board read the exhibits and began deliberations. Mr. Shanehsaz stated that the written comment received from Mr. Smith provided support and corroboration of the Board's decision to change the regulation. The Pharmacist-In-Charge is not in control of the staffing budget for the pharmacy, which makes the current regulation useless in providing the Pharmacist-In-Charge regulatory support with regard to staffing. Changing the regulation to make the facility licensee holder responsible for required staffing provides a means for the pharmacist to file a complaint if the required staffing is not provided. This regulatory requirement is also reviewed during pharmacy inspections completed by the Pharmacy Compliance officer. A motion to approve the proposed regulation 3.8 as written was made by Mr. Shanehsaz and seconded by Ms. Robbins. The motion unanimously carried.

Statutory and Regulatory Discussion

- Practitioner/Pharmacy Ownership - No Report
- Provision for Disciplinary Action - No Report
- Pharmacy Technician Regulation - No Report
- Clarification of §2512(e)(f), Inactive Status - No Report
- Review of Crimes Listing – currently in review by the legislative committee

NEW BUSINESS

Public Hearing Proposed Changes to Regulation 5.1.7

Ms. Kelly called the hearing to order. The Board members introduced themselves for the record. The purpose of the hearing is for the board to consider adoption of proposed amendments to rules and regulations. The proposed changes affect regulation 5.1.7. Ms. Kelly submitted exhibits of public hearing notices that were published in the Delaware State News and the News Journal. Written comment was received from Road Runner Pharmacy which included a letter from AVMA sent to FDA Center for Veterinary Medicine. Comment was presented from Andrew Wilson; Medical Society of Delaware. He stated the Medical Society was in support of the proposed changes. The written comment period will be held open for an additional 15 days. Ms. Kelly asked that deliberations of proposed regulations be added to the November 18, 2015 agenda.

Ms. Esposito read into the record the following ratifications:

Pharmacist and Intern Licensure Approval Ratifications

Pharmacist: A1-0004835 Bhumi Brandon Dicorato
A1-0004836 Alena S. Tarabrina
A1-0004837 Elizabeth Wathiri Ikiki
A1-0004838 Jason H. Chan
A1-0004839 Chelsey M. McIntyre
A1-0004840 Bozena Karwowska
A1-0004841 Deenaz A Narvel
A1-0004842 Joseph A. Lofaro
A1-0004843 Sara Elizabeth Knoll
A1-0004844 Joseph Michael Mulroy
A1-0004845 Ghislain Ketcha Tchemy
A1-0004846 Christopher J. Duffy
A1-0004847 Tameko Janelle Roberson
A1-0004848 Kirbie D. Hanlon
A1-0004849 Jade V. English
A1-0004850 Lauren Emilee Ruf
A1-0004851 Brittany Lynn Coleman
A1-0004852 Betsy George Daniel

A1-0004853	Amanda Benak
A1-0004854	Robert Y. Scharr
A1-0004855	Melissa G. Covert
A1-0004856	Quynh Nhu Thi Dao
A1-0004857	Palmer T. Wetzel, III
A1-0004858	Patrick Daniel Baker
A1-0004859	Matthew J. Lord
A1-0004860	Michael C. Dejos

A motion was made by Mr. Shanehsaz and seconded by Ms. Ms. Robbins to approve the ratification of the Pharmacist applications. The motion unanimously carried.

Pharmacist Intern:

A7-0002404	Cavan P. O'Kane
A7-0002405	Harish Chhibba
A7-0002406	Robert M Bond
A7-0002407	Komal V. Prajapati

Non-Resident Pharmacy Licensure Approval Ratifications

A9-0001704 Jay Pharmacy of Jay Fla, Inc.
A9-0001705 Barnes Healthcare of Florida, LLC
A9-0001706 Community Surgical Supply of Toms River, Inc.
A9-0001707 Hopkinton Drug. Inc.
A9-0001708 Liberty Medical, LLC d/b/a Liberty Medical Supply
A9-0001709 Catamaran Home Delivery
A9-0001710 BrivoRx
A9-0001711 BrivoRx
A9-0001712 Burman's Media Pharmacy, LLC
A9-0001713 Burman's Apothecary, LLC
A9-0001714 Omnicare Pharmacies of Pennsylvanina West LLC DBA Omnicare of Pittsburgh
A9-0001715 Heartland Pharmacy of Pennsylvania, LLC
A9-0001716 Infinite Care Development LLC
A9-0001717 Omni Pharmacy Services, LLC
A9-0001718 Alvarez Pharmacy & Discount Inc
A9-0001719 RepublicRx Specialty Pharmacy
A9-0001720 Pharmacy Consultants, LLC
A9-0001721 DIVVYMED, LLC dba DIVVYDOSE
A9-0001722 OnePoint Patient Care
A9-0001723 DeliverCareRx Pharmacy
A9-0001724 Hollis Prescription Center, Inc.
A9-0001725 US Specialty Care, LLC
A9-0001726 Infiniti Pharmacy and Infusion Services, Inc.
A9-0001727 Pentec Health, Inc.
A9-0001728 Hospital Pharmaceutical Consulting
A9-0001729 Halsted Pharmacy
A9-0001730 Liberty for All Pharmacy 2, Inc.
A9-0001731 PersonifilRx, LLC
A9-0001732 AxelaCare Health Solutions, LLC
A9-0001733 Heartland Healthcare Services, LLC
A9-0001734 Serquinox LLC dba AxelaCare
A9-0001735 AxelaCare Health Solutions, LLC
A9-0001736 US Med, LLC
A9-0001737 Advanced Rx Pharmacy 060
A9-0001738 Center City Pharmacy
A9-0001739 Mission Pharmacy
A9-0001740 Opus RX

A9-0001741 Glen Rx Drugs, Inc dba Astro Pharmacy

A motion was made by Mr. Shanehsaz and seconded by Ms. Robbins to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A4-0000787	PharMedium Services, LLC
A4-0002234	APL Logistics Warehouse Management Services, Inc
A4-0002235	APL Logistics Warehouse Management Services, Inc
A4-0002236	Blessings International
A4-0002237	Legacy Pharmaceutical Packaging, LLC
A4-0002238	Pharmacia & Upjohn Company LLC
A4-0002239	Letco Medical LLC
A4-0002240	Cerilliant Corporation
A4-0002241	Synergy Rx Express, LLC
A4-0002242	Unique Pharmaceuticals LTD
A4-0002243	Cardinal Health dba Specialty Pharmaceutical Services
A4-0002244	PureTek Corporation
A4-0002245	Exel Inc.
A4-0002246	Sigma Aldrich, Inc.
A4-0002248	QuVa Pharma, Inc.
A4-0002249	Cardinal Health dba Metro Medical Supply
A4-0002250	Cardinal Health dba Metro Medical Supply

A motion was made by Mr. Shanehsaz and seconded by Ms. Robbins to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Dispensers

A2-0000136 Sleepcircle

A motion was made by Mr. Shanehsaz and seconded by Ms. Robbins to approve the ratification of the Medical Gas Dispenser applications. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification

A3-0000990 Shayona Health Inc. DBA Greenhill Pharmacy
A3-0000991 Nanticoke Pharmacy, LLC

A motion was made by Mr. Shanehsaz and seconded by Ms. Robbins to approve the ratification of the Retail Pharmacy applications. The motion unanimously carried.

Retail Pharmacy Temporary Licensure Approval Ratification

None

Outsourcing Facility

AA-0000014	SCA Pharmaceuticals, LLC
AA-0000013	Avella of Deer Valley
AA-0000015	QuVa Pharma, Inc.
AA-0000009	PharMedium Services, LLC

A motion was made by Mr. Shanehsaz and seconded by Ms. Robbins to approve the ratification of the Outsourcing Facility applications. The motion unanimously carried.

Pharmacist-In-Charge Interviews

Ms. Robbins conducted PIC interviews with:
Brenda Matthews, CVS #3042 Bear, DE

Judy Balcombe, Walgreens #11078 New Castle, DE

Board Review of Consent Agreement

Gerard Mengang, a motion to approve the Consent Agreement as written was made by Ms. Robbins and seconded by Ms. Martini. Ms. Esposito recused herself and the motion carried.

Board Review of Applications by DAG

Care 4 L.P., a motion to approve was made by Mr. Shanehsaz and seconded by Ms. Wallner. The motion carried.

Advanced Care Scripts, a motion to approve was made by Ms. Robbins and seconded by Mr. Shanehsaz. The motion carried.

Jack P Herick Inc. d/b/a: Glade Drugs, a motion to approve was made by Mr. Galloway and seconded by Mr. Shanehsaz. The motion carried.

BDI, Inc., a motion to approve was made by Mr. Shanehsaz and seconded by Mr. Galloway. The motion carried.

ASCO Healthcare, LLC. d/b/a Omni Care of Salisbury, a motion to approve was made by Ms. Robbins and seconded by Ms. Martini. The motion carried.

ASCO Healthcare, LLC. d/b/a Omni Care of Annapolis Junction, a motion to approve was made by Ms. Robbins and seconded by Ms. Martini. The motion carried.

Zishan S Khan, a motion to approve was made by Mr. Shanehsaz and seconded by Mr. Galloway. The motion carried.

Continuing Education Approval

None

COMMITTEE REPORTS

Legislative – Joli Martini, Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz and David Dryden

The committee continues to review the current crimes listing in comparison to similar healthcare professions. The next scheduled meeting will be on November 18, 2015 immediately following the Board of Pharmacy meeting.

Continuing Education – Joli Martini, Bonnie Wallner, Tejal Patel and David Dryden:

Ms. Robbins informed the Board that DPS would be offering continuing education courses on October 30, 2015.

Consumer Affairs – Ken Sellers, Jay Galloway and Julia Wheatley

No Report

Professional Liaisons – Kim Robbins and Tejal Patel:

No Report

Controlled Substance Liaisons – Kenneth Sellers, Tejal Patel, Jay Galloway and David Dryden:

Mr. Shanehsaz reported that the Controlled Substance Committee is continuing its work on “Safe Opioid Prescribing” regulations.

Patient Safety Committee – Michelle McCreary (Chair), Kenneth Sellers, Tejal Patel, Kimberly Robbins, Susan Esposito, Joli Martini, Hooshang Shanehsaz, Jay Patel

Ms. McCreary reported the committee met prior to today’s meeting. The committee is continuing its work reviewing disciplinary actions for violation of statute. They will be shifting their discussion to the PMP and reporting of all non-scheduled drugs.

COMMITTEE UPDATES REGARDING PROPOSED REGULATIONS

Collaborative Care Committee – Bonnie Wallner, Cheri Briggs, Cheryl Heiks, Drew Wilson, Deborah Hamilton, Joli Martini, Julie Miro-Wenger, Mark Thompson, Mike Perza, Nick Biasotto, Pooja Dogra, Tejal Patel, Terri Corbo, William Harbester, David Dryden:

Mr. Shanehsaz stated that he contacted Ms. Julie Miro-Wenger and she responded by email stating there have been no meetings held since prior to May of this year. She also stated that Pharmacists believe that there is no legislation that prevents them from working in a collaborative manner. Therefore we have stopped pushing the issue. Mr. Shanehsaz strongly feels as though this is still a very important issue that should be reviewed and resolved. . Mr. Shanehsaz stated that in 48 states, pharmacists' scope of practice allows for collaborative practice agreements (CPA's) with prescribers. Delaware is not one of them. Mr. Shanehsaz stated that collaborative care provides a means to service underserved areas. This would be very beneficial here in the state. Mr. Shanehsaz suggests that the committee be reactivated in the near future to assist with providing changes in collaborative care for Delaware.

BOARD CORRESPONDENCE

None

EXECUTIVE SECRETARY, INSPECTION & PMP REPORT - David Dryden, Michelle McCreary, Samantha Nettesheim

Mr. Dryden was not available to attend this meeting. He was away attending the National Association of States Controlled Substance Authorities (NASCSA) conference at this time.

Ms. McCreary reported that she has completed the following inspections:

- 2 – Opening Inspections
- 2 - Remodel Inspection
- 1 – Medical Gas Dispenser Inspection
- 3 – Re-Inspections related to violations
- 1 – Wholesale Distributor Inspection
- 1 – Assisted the FDA with Routine Sterile Compounding Inspection over a 3 day period

NEWSLETTER UPDATES

Newsletter will be published on November 15, 2015

OTHER BUSINESS BEFORE THE BOARD

None

PUBLIC COMMENT

Mr. Jeff Lentowski wanted to know how the board defines “fully trained technician”? The Board responded by referring Mr. Lentowski to Regulation 19 of the Boards rules and regulations. Mr. Lentowski asked what the repercussion of the new regulation would be. The Board responded by stating that if staffing issues arise a complaint should be filed with the Division of Professional Regulation against the facility licensee for non-compliance of Pharmacy regulation. This is all contingent upon the approval of proposed regulations changes to regulation 5.1.7.

NEXT SCHEDULED MEETING

The next meeting is scheduled for November 18, 2015 at 9:30 Am., Conference Room A 2nd floor.

ADJOURNMENT

There being no other business before the Board a motion to adjourn the meeting was made by Ms. Martini, and seconded by Mr. Shanehsaz at 11:22 am. The motion unanimously carried.

Respectfully submitted,



Christine Mast
Administrative Specialist III
Liaison, Board of Pharmacy